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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,755	10/30/2001	Toshihiro Shimizu	2522 US2P	1478

23115 7590 08/08/2006

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,755	SHIMIZU ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,9,11-19,21-24,29,31,50 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,9,11-19,21-24,29,31,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/19/06 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 7, 9, 11-19, 21-24, 29, 31, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg (US 6,132,770), in view of Watanabe et al. (Biol. Pharm. Bull. Vol. 18, No. 9).

Lundberg teaches an effervescent tablet comprising mixture of enteric-coated pellets (beads, particles, granules) containing proton pump inhibitor (ppi) core (acid-labile active substance) (column 3, lines 59 through column 4, lines 1-19). The core material is chosen from celluloses, sugar, non-pareils, or mixture thereof, having size of

0.1-4 mm (100-4000 μm) (column 8, lines 11-54). The ppi is mixed with filler, binder, lubricant, disintegrant, surfactant, other additives, and alkaline reacting agent (basic salt), including, calcium and magnesium salts (column 8, lines 55 through column 9, lines 1-5). The filler, binder, lubricant, disintegrant, surfactant, and other additives, including sodium lauryl sulfate, microcrystalline cellulose, mannitol, and hydroxypropyl cellulose are disclosed in column 22, lines 53-57). The pellets are coated with one or more enteric coating layers comprising methacrylic acid copolymers, and an over coating layer (column 10, lines 16 through column 11, lines 1-21). The coated pellets are compressed into tablets having hardness of 51-100 N (which if converted into kg would fall within the claimed range). Lundberg further teaches the tablet disintegrates in liquid at about 55 seconds (see examples).

It is noted that Lundberg does not expressly teach the claimed amounts of the ingredients of claims 14-16. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is noted that Lundberg does not expressly teach the oral disintegration time.

Watanabe teaches a rapid disintegrate compressed tablet comprising crystalline cellulose and low-substituted hydroxypropyl cellulose (L-HPC) (see page 1308, materials and methods section). The tablet which is rapidly disintegrated and dissolved

in the mouth within 30 second, and having a crushing strength of 8-18 kg (see page 1308, and page 1309, results and discussion section). Thus, it would have been obvious for one of ordinary skill in the art to prepare the effervescent tablet of Lundberg using crystalline cellulose and L-HPC in view of the teaching of Watanabe to obtain the claimed invention, because the references teach the advantageous results in the use of similar disintegrating agents for the same purpose, such as, Lundberg teaches the effervescent tablet is especially suitable for patients with swallowing disorders and in pediatrics (column 3, lines 53-55), and Watanabe teaches that it is necessary to develop a new type of tablet having the characteristics of rapid disintegration and dissolution in saliva suitable for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308).

Response to Arguments

Applicant's arguments filed 05/19/06 have been fully considered but they are not persuasive.

Applicant argues that the effervescent tablets taught by Lundberg are not designed to dissolved in the oral cavity and cannot comfortably be completely dissolved in the oral cavity. Therefore, applicant request withdrawal of the 103(a) rejection over Lundberg. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.

1986). Lundberg is cited in view of Watanabe for the teaching of a rapidly disintegrate compressed tablet that dissolved in the mouth within 30 second (see page 1308, and page 1309, results and discussion section). Watanabe further teaches that it is necessary to develop a new type of tablet having the characteristics of rapid disintegration and dissolution in saliva suitable for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cherukuri et al., Yoo et al., and Balkin are cited as of interest for the teachings of rapidly disintegrate dosage forms.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R 6:00 am to 4:30 pm; Thurs. (telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Patent Examiner
Art Unit 1615